ProPerSeals
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ProPer FAQs
(Industry)

FOOD AND DRUGS AUTHORITY FDA GHANA

AfCFTA Creating One African Market

African Union

THE AFROCHAMPIONS INITIATIVE

Frequently Asked Questions

Q1. What is the ProPer Alliance?

Answer:

- The Alliance is an International network of African Union partners promoting the successful use of technology to advance the supply chain regulatory aspects of the AfCFTA implementation process. The Alliance was convened through the efforts of the AU and AfroChampions.

Q2. What are the costs involved and who will bear them?

Answer:

- The service is free for level 1 and 2 (L2 & L3) adoption and verifications (e.g. consumers checking product FDA numbers and using batch numbers to confirm the right expiry date of products). The cost for these services is borne by the ProPer Alliance on behalf of the AU and the FDA on behalf of government of Ghana.

- However, at levels 3 and 4 (L3 & L4), Brand Owners are expected to acquire Seals from vetted Solution Providers at a regulated fee. The exact amount is dependent on the volumes required and the delivery point of the seals. Costs are expected to be as low as 1% of cost of the product.

- The FDA shall cater for the costs associated with publicity and stakeholders engagements.

Q3. Who will provide the labels?

Answer:

- The ProPer Seals can be pre-embossed on printed labels and supplied by ProPer Agents/Solution Providers registered on the platform and whose technologies have been successfully integrated. The AU's partners has provided the resources for the pilot labels which have been applied on demo products.

Q4. How would consumers with feature phones be able to verify the labels?

Answer:

- Such consumers will verify the labels using a USSD code.

Q5. How does a product verification happen using GS1 serial code?

Answer:

- ProPer is integrating directly with technology providers in the serialisation industry, thus allowing consumers to verify products throughout the ProPer ecosystem.

- The interface for this interoperability is already in place based on a turnkey solution so deployment for each new solution provider takes just a few weeks, or even days depending on the readiness of that provider.

- The ProPer Alliance has already funded and provided the pilot GS1 serialisation system on demo products.

Q6. How does the system identify falsified products with genuine FDA registration number?

Answer:

- The system has different levels of verification. Though not all products overtly carry FDA numbers even when they are registered, consumers can alternatively verify products at the Levels 1 and 2 verification using barcodes and batch numbers. Some unscrupulous market players however tamper with expiry dates on products putting consumers at risk. Level 2 verification tackles this challenge by enabling verification with Batch Numbers and linkage to original data.

  Then there are those super sensitive or highly targeted products (listed in Appendix 5) where outright falsification exist. Level 3 verification kicks in for those products. Brand Owners must apply a unique Seal obtained from ProPer (Solution Providers) to each unit of every Appendix 5 product they make or sell. Fakers will not be able to obtain these Seals because issuance is controlled centrally, and the products are tracked through the Levels 3 and 4 lenses providing complete visibility to the regulator.

Q7. How does the system deal with falsified products that bear codes of Seals for genuine products?

Answer:

- No two products bear the same code; thus, a faker will need to buy as many units of the product it intends to falsify. This will make the falsification economically non-viable. If the same code is used for more than one product the system will trigger an alarm for investigations; and for a level 4 verification information on location of breach will facilitate the investigation.

Q8. What are some of the benefits of ProPer to industry?

Answer:

- Traceability and product unit-level authentication have become widespread worldwide. Thus, Ghana cannot afford to stay behind and still sustain a competitive industry. Many countries in the world are implementing systems to prevent illegal trade and related risks. Studies show that in the pharmaceutical sector alone at least 200 US million dollars of value is being creamed off by unregistered players and other illicit traders who are not bothered to comply with the expenses of regulation. This takes business away from legitimate industry players. When the benefits of rooting out these market share stealers are computed they far outweigh any costs of Seals. Then there is the benefit of being able to connect with consumers and understand market trends in real time and adjust trading strategies etc.

- Furthermore, anytime counterfeiters, smugglers and other illegal traders are removed from the market due to systems like ProPer, consumer confidence grows, boosting sales. So even though industry is required to spend a little for levels 3 and 4 (and nothing for levels 1 and 2), that amount will be more than recouped because the system will filter out illicit companies that are today undermining brand equity, in addition to stealing market share.

Q9. How will this new solution impact how the industry does business from a logistics point of view?

Answer:

- Whilst there will be some minimal adjustment requirements, they are reasonable. The primary shift is the need to serialise products for Levels 3 and 4. However, due to wide adoption of serialisation worldwide, many factories around the world are already equipped with the necessary tools. Growing sales volumes of serialisation instruments has led to considerable price falls, minimising the cost burden to industry.

- At level 4 alone, there is a requirement for businesses to equip themselves with scanners for event data management. Said scanners will however be app-based so that normal phones can be used. It is important to emphasise that all ProPer solutions are developed with global trends in mind. They therefore align perfectly with production and operational systems worldwide that are likewise compliant with global standards. Across the major production hubs around the world, most factories already have the mechanisms in place to apply unique serials. Ghana's conformance with these trends is thus inevitable.

Q10. What is the track record of ProPer?

Answer:

- ProPer as an Initiative of the African Union and its strategic partners is linked to other AU initiatives in a very similar context that have been validating and tracking Health records (Test results and Vaccination certificates) of over 3 million travellers during the pandemic. ProPer leverages the traceability infrastructure developed for PanaBIOS and similar programs that is already in use in 21 countries across Africa. These platforms have been in operation since 2020 without a glitch.

Q11. What if my Solution Provider is not on the ProPer Platform?

Answer:

- They can be integrated onto the ProPer Platform provided they meet the ISO, GS1, and AU Open Corridors framework technical standards. If not, then you will need to switch Solution Providers.

Q12. How would a patient who gets a strip/tablet of a drug (not the box/package) which bears no FDA Number/Batch Number/Seal from the Pharmacy shop verify the product?

Answer:

- Education of stakeholders at all levels will include purchase of medicines from licensed pharmacies or OTCS, who in turn will be educated to demonstrate the genuineness of their products to such clients. With the move towards mono carton sale of medicines by the WHO, dispensing guidelines are to move towards mono carton sale of drugs and so more and more medicines are being sold in mono cartons to patients. These cartons normally have all the information a patient needs for the dosage administered. ProPer aligns with this trend.

Q13. What is the process of Seals stocking and Management?

Answer:

- Brand Owners whose products are selected for Level 3 and/or 4 can get any number of Seals they demand. Based on their production volume forecasts, we will further engage with them to document their sales patterns. The demand forecast for these products shall be mapped to all the Solution Providers. Essentially, Solution Providers will then be given the targets they have to meet based on their clients' portfolios for Seals to be provided to meet 3 months of demand and then replenished from time to time. We confirm that we have already secured production commitments for the pilot volumes and will meet all demand once the FDA signs off on the initial product categories for the Level 3 rollout.

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